



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HFF-35

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Food and Drug Administration  
Cincinnati District Office  
Central Region  
6751 Steger Drive  
Cincinnati, OH 45237-3097  
Telephone: (513) 679-2700  
FAX: (513) 679-2771

April 30, 2000

WARNING LETTER  
CIN-WL 00-2680

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. Donnie Tyler  
625 Horn Road  
Harrodsburg, KY 40422

Dear Mr. Tyler:

The U. S. Food and Drug Administration (FDA) was informed by the USDA that tissue from a dairy cow slaughtered on or around December 2, 1999, was found to contain an illegal drug residue. The USDA laboratory's analytical report #346499, shows that the muscle, liver, and kidney tissues of the referenced animal contained Tilimicosin at levels of 0.31 ppm; 5.70 ppm; and 6.90 ppm, respectively. The established tolerance level for this drug in the liver tissue of cows intended for slaughter as human food is 1.2 ppm. This cow was offered for slaughter as food in violation of Sections 402 (a)(2)(C) (ii), and 402 (a)(4) and Section 501 (a)(5) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). An investigation at your dairy operation conducted by our investigator on April 12, 2000, determined that this cow belonged to you.

The FD&C Act is a strict liability statute, which requires that anyone in a position of authority and power to prevent violations of the ACT take all reasonable steps to do so. The failure to act to prevent unlawful sales violates the law even when no intent to do any wrongful act existed. In-addition, the FD&C Act prohibits adulterated food from being introduced or delivered for introduction into interstate commerce. The Federal Courts have also held that animals intended for slaughter are food. Therefore, animals which contain illegal levels of drug residues are adulterated food when intended for, or bought for slaughter.

A food is adulterated under Section 402 (a)(2)(C) (ii) of the Act, if it contains a new animal drug which is unsafe within the meaning of Section 512 and Section 402 (a)(4) if the food has been held under insanitary conditions whereby it may have been rendered injurious to health. As it applies in this instance, "insanitary conditions", refers to your lack of records for animals which you medicate. Consequently, you held an animal, which was ultimately offered for sale for food, under conditions, which are so inadequate that a medicated animal bearing possibly harmful drug residues was likely to enter the food supply. A drug is adulterated under Section 501 (a)(5) if it is administered in a manner other than in accordance with the directions specified in the labeling, thereby making it unsafe within the meaning of Section 512(a)(1)(B).

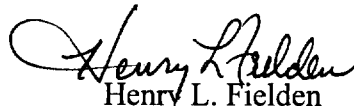
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Please notify this office within fifteen (15) working days of the receipt of this letter of the specific steps that you have taken to correct the noted violations. Your response should include an explanation of each step being taken to prevent the recurrence of similar violations in future. If your corrective action can not be completed within 15 working days, please state the reason for the delay, and the time frame within which the necessary corrections will be completed.

Failure to promptly implement adequate corrections may result in further regulatory action without such as seizure and/or injunction, without additional notice.

Your response should be directed to the U. S. Food and Drug Administration, Cincinnati District Office, 6751 Steger Drive, Cincinnati, Ohio 45237-3097, ATTN: David C. Radle, Tissue Residue Monitor.

Sincerely,

  
Henry L. Fielden  
District Director  
Cincinnati District